UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

PLAINTIFFS' CONTROVERTING STATEMENT OF FACTS IN OPPOSITION TO BARD'S MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION

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EXHIBIT 1

IN THE CIRCUIT COURT OF THE 17TH JUDICIAL CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

CLARE AUSTIN, Plaintiff, v. C.R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, MATTHEW ROBBINS, M.D., and CLEVELAND CLINIC FLORIDA, Defendants.	§	Case No. CACE-15-008373 Div: 07

- - -

AUGUST 16, 2016

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- - -

Videotaped deposition of DANIEL ORMS, held at Miami Marriott Dadeland, 9090 South Dadeland Boulevard, Miami, Florida, 33156, commencing at 9:20 a.m., on the above date, before Trina B. Wellslager, Registered Professional Reporter and Notary Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Q. -- of the Recovery filter, correct?
A. Uh-hum.
Q. Do you remember what year that began to be marketed?
A. I don't.
Q. Does 2005 ring a bell?
A. It sounds about right.
Q. Okay. And was it originally cleared with the retrievable indication?
A. I believe not.
Q. Okay. So a permanent one and then the --
A. Permanent, and then the retrievable indication followed.
Q. Do you remember how long it was in between?
A. I don't.
Q. Okay. Do you remember hearing of any physicians, although it wasn't approved for retrievability, taking it out anyway?
A. So using it off label, is that what you're asking?
Q. I'm asking you if you ever heard of any physicians, despite it not being indicated for retrievability, taking it out anyway?
A. Yes.

Q. Okay. And when did you hear that?
A. I can't give you specifics. I can -- like when you said do you remember, I do remember physicians using it, again, what is off label, so out of indication. I can't tell you one exactly.
Q. Okay. Do you remember how many times you became aware of physicians removing the G2 filter when it didn't have a retrievable indication?
A. No.
Q. Okay. But it happened in your territory.
A. Yes.
Q. Okay. Did you hear about it happening in any other territories?
A. Yes.
Q. Okay. So this was understood that physicians were removing the G2 filter prior to it having a removable indication? Retrievable indication, excuse me.
MR. BROWN: Object to the form.
A. Yeah, physicians were choosing to use the device off label.
Q. Okay. Do you know why the Recovery filter was modified?
A. Do I know why?

EXHIBIT 2
(Filed Under Seal)

EXHIBIT 3
(Filed Under Seal)

EXHIBIT 4

Ramon Rossi Lopez - rlopez@lopezmchugh.com
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Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **DECLARATION OF DAVID KESSLER**

I, David Kessler, declare and state as follows:

1. I am over the age of 18 and the statements made below are true and correct of my own personal knowledge, unless otherwise stated.

2. I am one of the experts retained by Plaintiffs in the *In Re Bard IVC Filters Products Liability Litigation* case, No. MD-15-02641-PHX-DGC, pending in the District of Arizona.

3. I previously authored reports in this case dated September 26, 2016, and March 3, 2017.

4. As part of my work on this case, I have been asked to provide additional opinions relating to certain facts and issues recently raised by Bard in connection with its Motion for Summary Judgment re Preemption (Doc. 5396).

5. My supplemental report dated July 15, 2017, contains these additional opinions, which I incorporate into this Declaration by reference. I also incorporate my September 26, 2016, and March 3, 2017, reports into this Declaration by reference.

6. If asked, I will testify consistently with the statements made in my September 26, 2016, March 3, 2017, and July 15, 2017, reports.

Pursuant to 28 U.S.C. Section 1746, I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on this 28th day of August 2017.

David Kessler

EXHIBIT 5
(Redacted and Filed Under Seal)

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	) No.) MD-15-02641-PHX-DGC

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF ROBERT MICHAEL CARR, JR.

Phoenix, Arizona
June 6, 2017
9:00 a.m.

REPORTED BY:

Robin L. B. Osterode, RPR, CSR

AZ Certified Reporter No. 50695

Q. Part 870.3375, which are -- it's a regulation relating to cardiovascular/intravascular filters. Now, that indicates three types of additional items that an IVC filter must comply with to get 510(k) clearance. Correct?

A. Yes.

Q. And those are related to IVC filters, but not limited to IVC filters. Right?

MR. NORTH: Objection to the form.

THE WITNESS: I believe they are limited to IVC filters.

BY MR. CLARK:

Q. Okay, so that -- and that's what I want to understand. Are there any types of filters that are not -- that aren't placed in the inferior vena cava that would also be subject to this, if you know?

A. Not to my knowledge, no.

Q. Do you have an understanding that these regulations that we've just talked about, the four regulations have not changed from 2002 through 2013 when all the sort of regulatory actions, so to speak, happened with respect to 510(k) clearance for the Recovery through Denali line of filters?

A. I know that they've been revised; I couldn't tell you the exact changes, but they have

certainly been revised.

Q. If I told you that there were no changes to these four regulations from 2002 through 2013, other than possibly formatting, would you have any reason to disagree with that?

A. No, not without looking at them.

Q. Now, with respect to your work with -- there's reference in the last statute that I -- I'm sorry, regulation that I showed you to three additional types of requirements for filters. One is ISO 10993. What is that requirement?

A. It's a requirement that outlines the biocompatibility testing, biological testing that medical devices, certain types of medical devices must undergo.

Q. And when you say "certain types of medical devices," that includes IVC filters. Correct?

A. It does.

Q. But there would potentially be other medical devices that would also have to comply with this ISO?

A. They do, to varying degrees, yes.

Q. Do you have any examples of other devices besides IVC filters that would have to comply with ISO 10993?

A. I believe all do. But it depends on their classification as to what testing you need to do.

Q. So all devices have to establish biocompatibility, but the testing that's needed to establish, that will vary, depending on the type of device. Fair?

A. Yes. Context of the patient or it's an implant, et cetera.

Q. What's the 510(k) Sterility Review Guidance and Revision of 2-12-90?

A. It's pretty self-explanatory. It's a guidance for testing for the sterility of a product.

Q. Is that -- does that apply to all products?

MR. NORTH: Objection to the form.

BY MR. CLARK:

Q. I'm sorry, does that apply to all medical devices?

A. No.

Q. Do you have an understanding of the types of medical devices that this requirement applies to?

A. Certainly implants. Those that are not -- some surgical tools that are usable it probably would not apply to directly; it's a bit different. They don't come sterile.

Q. So that -- that requirement is essentially

[redacted]

EXHIBIT 6
(Redacted and Filed Under Seal)

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters)

Products Liability Litigation)

----------) No. MD-15-02641-PHX-DGC

Do Not Disclose -

Subject to Further Confidentiality Review

This is the videotaped deposition of MURRAY R. ASCH, M.D., taken before Terry Wood, CSR, RPR, a court reporter, at Victoria Room, Residence Inn, 160 Consumers Drive, Whitby, Ontario, Canada, on the 2nd of May, 2016, at 9:13 a.m..

Reported by: Terry Wood, CSR (Ont.), RPR

Videographer: Jim Lopez

[redacted]

Q. All right. Dr. Asch, I want to talk to you now about that study.

What were you asked to do by Bard?

A. I was asked to recruit patients into the study and assess the safety and feasibility of both implanting the device, and removing the device to ensure that it was -- it was safe and lived up to their expectations of a retrievable device.

Q. And so part of the study was to see if these could be taken out, in fact, after a period of weeks?

A. Yes, the main --

MR. NORTH: Objection to the form. I'm sorry.

BY MR. BOATMAN:

Q. And was part of your analysis as to whether, in retrieval, the vein would be damaged in the removal process?

MR. NORTH: Objection to form.

THE DEPONENT: Yes.

BY MR. BOATMAN:

Q. You can answer. When you say it was -- would you call this a retrievability study?

A. Yes, absolutely.

Q. When you say a retrievability study, is that different than a safety study?

A. Yes, there are different aspects of any device and including an IVC filter. So an IVC filter has a function to perform in terms of remaining in position, in terms of protecting patients from pulmonary emboli, blot clots to the lungs. However, this study wasn't designed to test those things. This study was designed to ensure that the device could be safely removed.

Q. If you had been asked to do a safety study for the use of the filter long-term, would have the study been done differently?

A. Yes. There were different questions. The study would have been done differently with a different question.

Q. And give me some examples of how it would have been done differently?

A. Well, the design of scientific studies is a bit complex and challenging, depending upon the specific questions. So if we are looking for long-term safety of the device, I would then embark upon a long-term study, leaving the filter in for a

EXHIBIT 7

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
BEFORE THE HONORABLE ROBERT C. JONES, DISTRICT JUDGE
---o0o---

KEVIN PHILLIPS, an individual,	:	
Plaintiff,	:	No. 3:12-CV-344-RCJ-WGC
-vs-	:	February 2, 2015
C.R. BARD, INC., a foreign corporation, et al.,	:	Reno, Nevada
Defendants.	:	

TRANSCRIPT OF TESTIMONY OF SUZANNE PARISIAN, M.D.

APPEARANCES:

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FOR THE DEFENDANTS: RICHARD B. NORTH, JR., and MATTHEW B. LERNER
Attorneys at Law
Atlanta, Georgia

Reported by: Margaret E. Griener, CCR #3, FCRR
Official Reporter
400 South Virginia Street
Reno, Nevada 89501

(Appearances continued on page 2.)

on a particular topic.

A guidance document is -- can be two types. It can be made for the manufacturer industry, guidance documents to try to help them be aware of what the FDA requires, to help them get 510(k) clearances, for various different things to try to assist the industry.

There are also some guidances that include the information for the reviewer, too.

But typically guidances are designed to give access to industry of current FDA thinking, to try to help bring new products to the public, and try to make it, you know, easier to get products through the FDA.

Q And in 1999 the FDA produced a guidance document for the development of inferior vena cava filters, correct?

A It wasn't for the development, it was for a 510(k).

The guidance document was to help encourage the manufacturer to test certain things. It's not all inclusive. It's not a cookbook do this and then you have an IVF.

But it was to try to tell the manufacturer what you would need to provide the FDA to get clearance, 510(k) clearance. The manufacturer itself does all the development under good manufacturing of a new product. So it's basically based on a 510(k).

MR. NORTH: If we could show the witness Exhibit 2112.

EXHIBIT 8

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	) No. MD-15-02641-PHX-DGC

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CHRISTINE L. BRAUER, Ph.D.

WASHINGTON, D.C.

WEDNESDAY, AUGUST 2, 2017

9:07 A.M.

Reported by: Leslie A. Todd

Q Okay. When you say labeling, what are you talking about exactly?

A The instructions for use.

Q Okay. But that's not -- that's not all -- that's not how labeling is defined in a regulatory way, right? It's not just IFUs or other things that fall within the category of labeling?

A That's correct, sir.

Q And what -- what --

A The category of labeling can include additional materials.

Q For example?

A Labels that are physically attached.

Q What -- and that's it, just an IFU and labels that are physically attached?

A No, sir, it can include other things.

Q Well, I'm asking you that question, what does labeling entail in a regulatory sense?

A In a regulatory sense, it can entail the labels, the labeling or instructions for use, and it can also entail promotional materials.

Q All right. In fact, it can include any commune- -- any official communication by a

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS)
LIABILITY LITIGATION,) MD No.: 02641
_____)

Do Not Disclose - Subject to Further Confidentiality Review

VIDEOTAPED DEPOSITION OF KAY FULLER

Phoenix, Arizona

January 11, 2016

9:07 a.m.

REPORTED BY:

Robin L. B. Osterode, RPR, CSR

AZ Certified Reporter No. 50695

device.

Q. Okay. Now, Exhibit 3, which is --

What's your number on Exhibit 3?

MS. BLAS: It's Exhibit 117.

(Marked for identification Exhibit 117.)

BY MR. NATIONS:

Q. Let me show you Exhibit 117. The caption on this is "Guidance for our Industry and FDA Staff" -- "Guidance for Cardiovascular/Intravascular Filter 510(k) Submissions," and this was issued on November 16th, 1999. What is the purpose of this document?

A. As we just mentioned, this is a FDA-issued guidance document to help companies understand FDA's current thinking on what needs to go into a 510(k) submission for a cardiovascular/intravascular filter also known as an IVC filter. And in it it tells you, it gives, especially the regulatory people and the company the scope of this guidance document, as well as what -- what it is referring to and what it's not referring to. And it gives ideas on the type of preclinical testing that would be required to be included in that 510(k) submission, the performance-related characteristics of the device, how to both simulate it and in vivo-related

capabilities of the device.

And also it does refer to some clinical investigations, and then addressing any types of complications that the device might have, how to go about incorporating that information into your 510(k) application.

Q. Now, this is -- this is stamped by CDRH, which is the Center for Devices and Radiological Health. What's the relationship of CDRH to FDA?

A. The CDRH is one of several divisions at the FDA. The CDRH is the primary center that handles device-related submissions and applications.

Q. Okay.

A. It's the center that we would actually submit the 510(k) to.

Q. Under guidance for the 510(k) submissions, it says their devi -- the manu -- can you read that last part of that designation?

MS. BLAS: It's on the screen.

THE WITNESS: I'm sorry, the guidance --

BY MR. NATIONS:

Q. Yeah.

A. -- for cardiovascular/intravascular filter submissions --

Q. Yes.

A. -- that paragraph?
Q. Yes.
A. "This guidance document describes a means by which cardiovascular/intravascular filter devices may comply with the requirement of special controls for Class II devices." Do you want me to continue?
Q. Yes.
A. "Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate cardiovascular/intravascular filter device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurance of safety and effectiveness."
Q. So you have the guidance from this document, and then you have -- you're comparing to the predicate device?
A. That's correct.
Q. Is that primarily where the manufacturer gets their guidelines that they have to comply with?
A. It's -- it's one of the places. Again, this is a guidance document where we get, primarily, one of the requirements reside are in the Code of

Federal Regulation.

Q. Yes.

A. So there's a lot more detail in the regulation than in the guidance document.

Q. Okay.

A. Excuse me, could I have some water?

Q. Absolutely. Where's --

A. May I stand up for a minute?

MR. NATIONS: Yeah, let's take a break here, that's fine.

THE VIDEOGRAPHER: With the approval of counsel. Going off the record. The time is approximately 10:00 a.m.

(Recessed from 10:00 a.m. until 10:14 a.m.)

THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 10:14 a.m.

BY MR. NATIONS:

Q. Ms. Fuller, I'd like to direct your attention now to when you first went to work with Bard or when you were recruited at Bard. Tell us the facts surrounding that, would you, please.

A. I was approached by a recruiter, and they contacted me and I talked to them, they explained there was an opening at Bard for a senior regulatory

engineering way to design a bench test that could do that. The reason that's really important is you want to understand at what point does that metal fatigue and when does it break, such that you could improve the specifications of that metal to be more likely to be designed that the specifications would not only allow it not to break at that level, but to have some built-in reinforcements so that it would be able to endure longer stress before it would break. So there is certainly an engineering way to do that.

Q. Did you ever participate in or witness while you were at Bard before this submission, that a recommendation that a validated test method to assess fatigue resistance be developed?

A. I don't recall that.

Q. Okay. Did you ever get the answer to your question or did you get any -- not answer to the question, did you ever get substantive evidence of whether the proper sterilization had been done in the proper order to produce a safe product?

A. Well, there's two things in that question, so --

Q. All right.

A. -- I -- I was -- I had seen the sterilization validation to assure that the product

could be sterilized and packaged and stay sterile. I'd seen that. But what I had not seen was earlier testing that would have been conducted on the device, which at the time was this 10-year cycle testing. I had not seen a report that indicated in the report that the company had tested post-sterilized product. I never did see that report.

(Marked for identification Exhibit 126.)

BY MR. NATIONS:

Q. Okay. We're going to show you Exhibit 126. And see if you can --

MS. BLAS: Give me one second to get copies.

BY MR. NATIONS:

Q. I'll have you look at this.

MS. BLAS: Two seconds. Yeah, it's on the screen and the hard copies are coming.

It's on the screen, Howard. It's right here.

BY MR. NATIONS:

Q. And what does this document appear to be?

A. It looks like a copy of a cover letter to a 510(k) submission from IMPRA to the FDA.

Q. Okay. And is this the submission -- what -- what submission is this for?

MR. NORTH: 58B.

THE WITNESS: I'm just refreshing my memory of the questions that the FDA asked, and how we responded, so to answer your question.

MR. NORTH: How much time --

MS. DALY: 14.

THE WITNESS: There is some discussion about "the potential for vena cava filter to perforate the vessel being primarily due to the outward radial force that the filter elements exert onto the vena cava wall. If the force is too high, the localized pressure will tend to weaken the vessel wall and could cause it to fail."

And then we go on to describe how the original design inputs for the Recovery Filter was designed to be no greater than the Simon Nitinol Filter, the predicate filter. Appropriate mechanical test is the radial strength test, so yeah.

BY MR. NORTH:

Q. Not once in that letter, though, did you mention that you were concerned about the Recovery Filter, because this cycle testing that you've referenced, 10-year testing had not been performed on post-sterilized filters, did you?

A. That's correct.

EXHIBIT 10

Katrina Newton, et al v.
C.R. Bard, Inc., et al

Kay Fuller
November 09, 2010

Moretti Group
471 W. South Street
Suite 41B
Kalamazoo, MI 49007
800-536-0804

Original File 110910KF.txt
Min-U-Script®

A. It's my opinion that it did.
Q. In what way?
A. Well, I decided one of the biggest concerns I had is that the FDA requires a company to validate their product will perform as intended. There are different ways to validate a product. There are bench testing methodologies; there are animal studies; and then sometimes there are clinical studies. These are all types of validation tests. My concern was that one of the most important validation tests for this product from a performance standpoint, was the fatigue testing that I believe occurred with the Endura-Tech fatigue tester.

My recollection is they had conducted pretty extensive fatigue testing, which replicated, I believe, up to at least ten years of simulated use. In other words, ten years of simulated implantation. And my recollection is that that fatigue testing did yield results that showed that the product could withstand over ten years of sumulated use. However, and this was my biggest concern, they had not tested it on a product that had been ethyleenoxide sterilized. They had tested it prior to that sterilization process. And my big concern was that nitinol being a shaped memory metal

that is temperature sensitive metal, I did not know whether nitinol might be affected by the sterilization process. In other words, one of the things that I don't believe we had a satisfactory data on, was whether or not the recovery filter after sterilization, would pass a ten-year simulated-use fatigue test. Ethyleenoxide sterilization involves chemical, moisture, temperature and pressure environment in order to sterilize the product.

Q. Did you express these concerns to the other members of the team and management?

A. Yes, I did.

Q. And what was the response that you received from management?

A. Various responses that were not heeding my concerns.

Q. Could you give me some examples?

A. I believe I wrote some e-mails. Especially when I first discovered that the testing had occurred on pre-sterilized products. Now, I would like to take a moment to explain that it's my recollection that many of these tests had been conducted by the company NMT rather than Bard.

Q. All right.

A. And so I can't recall I need to say. But I believe

some of this original fatigue testing occurred at NMT. As NMT as I recall was the company that actually developed this device in the early stages. And I believe Bard purchased it from NMT, and some of the employees from NMT joined Bard, if I recall that correctly.

And so part of the pressure on the team was that there had been so many delays in getting this through the 510(k) process with the FDA, that a few years had gone by, the company had hoped to already have this product on the market, and additional testing would add to the delay.

Q. So, are you suggesting that it would cost the company money in sales to do the testing that you were recommending to determine whether the fatigability of the filter or the fracture rate of the filter would be impacted by the sterilization process?

MS. TAPLEY DALY: Object to the form. You, can answer.

THE WITNESS: Yeah, I might say it a little bit differently. I don't want to speculate on whether the company would lose sales or not. It may be a foregone conclusion that you can't make a sale until you get FDA clearance on your product. And so

what my understanding of the decision-making was that additional testing may delay getting the 510(k) cleared. There was also some conflict within the time, frankly, that I was concerned about.

Q. What was that?

A. One of the company engineers from NMT had, I believe, helped develop the product while he was at NMT, and he ended up joining Bard and became an important project leader, I believe, for this project at Bard. I believe he may have been involved in some of this testing that may have occurred at NMT in the early development of the product, and there were some disagreements on whether or not this additional testing was really necessary. But I believe this particular engineer has potential conflict in the pressure on him to get the product out, you know, to the market, as well as his early work on the product. So he had the most pressure on him, frankly, historically.

Q. Who was that?

A. Robert Carr.

Q. Other than the response that we needed to -- we meaning Bard, Bard needed to get the 510(k) approved and get the product to market and Mr. Carr's suggestion that the additional fatigue testing after

sterilization was not needed, was there any other response to your suggestion for fatigue testing?

MS. TAPLEY DALY: Object to the form. I'm sorry, Dean, object to the form. You have misstated her testimony, but she can answer subject to that objection.

THE WITNESS: Can you restate the question?

MR. HARTLEY: Sure. Let me rephrase the question.

BY MR. HARTLEY:

Q. In addition to the items that you have mentioned to us already, was there any additional response to your suggestion that further fatigue testing after sterilization was needed?

A. I apologize, Dean. Can you ask me the question again?

Q. I believe you suggested to me, and I said -- my question to you earlier was, what was management's response to your suggestion that sterilization fatigue testing after sterilization should be accomplished, in light of what had been done with the fatigue testing on the recovery filter at that point in time, correct?

A. Yes.

Q. And then you mentioned to me that there was pressure

to get the product out and get it approved by FDA so that it could be marketed, correct?

A. I'd like to correct that slightly. The FDA did not approve this product. The FDA cleared this product.

Q. All right. But there was pressure to get the product cleared so it could get on to the market, correct?

A. Yes.

Q. And there was, in your words, a conflict within the team as to whether additional fatigue testing was even necessary?

A. I would say that is correct. I was not in the majority, in my opinion, I'll say.

Q. All right. And my question to you, then, was -- was there any other response from management other than those two items?

A. Response from management that additional fatigue testing wasn't necessary?

Q. Yes, ma'am.

A. I don't recall anything in particular, additional response from management, per se. However, I would say that management's actions continued to move the process forward. I did bring up some concerns about the failure investigation on the fractured filter, and the conclusions that were made in that report

EXHIBIT 11

Deposition of:

David Kessler , M.D.

July 31, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

Q And if in reviewing a 510(k) application the FDA wants the label changed, it can request it, correct?

A It's part of a negotiation with the company. There's a back and forth.

Q And, in fact, for the G2 -- G2 filter, the FDA requested a warning -- specific warning regarding the use of the filter in morbidly obese patients, correct?

A I'd have to go back. I think there was a request. I'd have to go back and actually understand that chronology with regard to morbidly obese. I do have it in my notes here.

Q Do you recall one way or the other whether a warning regarding morbidly obese patients was ultimately added to the G2 IFU?

A I have it here in my schedules exactly. Just let me be -- I believe so. Happy to check. Just give me a second and I can be double sure. Let me just see if I can... I'd have to double-check on that to be sure. I believe that's correct. But I think that there was a back and forth with the company.

Q You haven't spoken with any of the actual reviewers of Bard's 510(k)s, have you?

A I have not. I stayed with the record.

Q Are you going to offer any opinions that Bard, in designing, manufacturing and selling any of its IVC

see if I can find it for you. Let it be -- it's one of the great titles of an article. Let me just check the journal. Actually, I'm sorry. It's Journal of Vascular and Interventional Radiology. Let it be finale of seeing the safety and efficacy of inferior vena cava filters. If you go through this and if you look at the Denali, it clearly was not a study of safety and efficacy. It was a study of placement and retrievability.

MR. NORTH: Let's mark this.

(Exhibit 12 was marked for identification by the court reporter and is attached hereto.)

THE VIDEOGRAPHER: Twelve.

BY MR. NORTH:

Q No. 12 is the FDA's 1999 guidance regarding filters, correct?

A Yes, sir.

Q And you are familiar with that?

A I am. It superseded the '97 guidance. Yes, sir.

Q And you state in Exhibit 4, your second supplemental report, that this particular guidance is not specific to Bard filters, correct?

A It doesn't mention Bard filters at all.

Q But it is applicable to Bard filters, correct?

A It's not specific with regard to Bard filters.

Q Isn't it applicable to all IVC filters?

A It says -- all it says is "This guidance document describes the means by which cardiovascular intravascular filters may comply with the requirements of special controls." So it may -- I mean, it's there and it may provide -- it says exactly that. Companies can go their own direction, but they also can comply with the -- it's a roadmap. It's a guidance document with regard to that. It's not specific with regard to Bard. And we've seen -- I mean, continual evidence of that. You know, Bard designed its own migration testing. It changed it's migration -- it's own performance testing, it's own performance results. It changed what those standards were on its own independent of this guidance.

Q The guidance document does not tell you exactly how to perform a migration study, does it?

A Not only -- it certainly does not. There's not specificity in that, and you see it doesn't say what the performance standard is. It's not how to do it. It doesn't even say what the performance standard is. And you see that Bard changed those performance standards when it failed. The device failed.

Q You would agree that Bard's retrievable filters are cardiovascular intravascular filters, correct?